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C O N F I D E N T I A L SECTION 01 OF 06 BANGKOK 007335

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STATE PASS USTR FOR BWEISEL, CWILSON
STATE PASS USPTO FOR KHAUDA, KFERRITER
COMMERCE FOR JKELLY
HHS/OGHA FOR ABAHT, EELVANDER

E.O. 12958: DECL: 12/08/2016
TAGS: ECON ETRD KIPR TH
SUBJECT: NEXT STEPS FOR THAILAND'S COMPULSORY LICENSE BID

REF: BANGKOK 7133

Classified By: DCM A. Arvizu for reasons 1.4 (b) and (d).

¶1. (C) Summary: On November 29, the RTG Ministry of Public Health (MoPH) issued a statement announcing a compulsory license (CL) on efavirenz, a Merck-patented medicine used to treat HIV/AIDS patients. The Ministry's statement cited the high price of the drug as a barrier to access to effective HIV drugs, and declared its intention to import generic versions of the drug and also produce domestically. Supply issues may also have been a factor in MoPH's decision. Merck was not notified prior to the announcement and to date has not had the opportunity to meet with decision makers at the Ministry. While Thailand probably has complied with both its own law and the WTO in its action, the lack of prior consultation with Merck and the absence of any attempt to negotiate pricing with the U.S. firm weaken MoPH's arguments and suggest the MoPH is being heavily influenced by activist NGOs. We do not believe the major RTG economic ministries are aware of either the details or the implications of the MoPH decision, something we hope to remedy. Although many believe we are facing a fait accompli, it may yet be possible to avoid CL implementation: Merck plans to counter MoPH's announcement with a price reduction and, with USG help, hopes to salvage its patent. However, increasing numbers of HIV-positive patients and spiraling treatment costs may bring about further RTG moves on compulsory licenses. Embassy action request is contained in para 28. End Summary.

¶2. (U) This is an action request, see para 28.

¶3. (C) As reported in reftel, on November 29, the Ministry of Public Health's Department of Disease Control announced a compulsory license on efavirenz, an HIV/AIDS medicine patented in Thailand by U.S.-based pharmaceutical firm Merck & Co. Although both Embassy and Merck caught wind of the Ministry's intention soon before the announcement, no branch of the RTG attempted to give official notification beforehand. Embassy officers have subsequently contacted relevant RTG officials, NGO reps, and Merck representatives to obtain a more comprehensive picture of the facts surrounding the CL action, as well as the political and legal context of the decision.
¶4. (C) On December 4, Merck formally requested a meeting with the Minister of Public Health, Dr. Mongkol Na Songkhla, to discuss the Ministry's compulsory license of their product. According to Merck, the Minister's office suggested the meeting request be pushed down to the Director General of the Department of Disease Control, but Merck has yet to receive an official response and still hopes for a meeting

with the Minister. (Separately, the Minister of Commerce, Mr. Krirk-krai Jirapaet, has tentatively agreed to meet with Merck on December 20.)

How did it come to this?

¶5. (C) The use of efavirenz has rapidly increased in Thailand due to ever increasing numbers of HIV-positive patients and an RTG commitment in 2005 to supply antiretrovirals (ARV) to all eligible patients. A UNAIDS report earlier this year estimated that approximately 580,000 Thais are HIV-positive. Of these, only 133,000 are actually eligible for treatment, the rest either unaware of their HIV status, yet to show symptoms and not yet in need of treatment, or have such an advanced case of AIDS that drugs can not halt their decline in health. U.S. Center for Disease Control (CDC) estimates 92,000 Thais are now on ARV therapy. The RTG has set a goal to have 122,000 on treatment by the end of 2007. Most HIV-positive patients are on a locally produced first-line treatment known as GPO-vir, a combination of d4T, 3TC and nevirapine. However, 10 to 15 percent of patients have an adverse reaction to nevirapine or are otherwise unable to take the medicine. Merck's efavirenz is an effective substitute for nevirapine, but its use can triple the cost of treatment. Given Thailand's income level and a greater than one percent rate of HIV prevalence, Merck says it sells efavirenz at a "no-profit" price, its lowest price globally. Approximately 13,000 patients receive efavirenz through the government's health insurance programs and several thousand more outside these programs. With a lower price, MoPH has said it hopes to move up to 100,000 patients to a therapy including efavirenz to avoid the reactions to nevirapine altogether. We believe MoPH's plans to dramatically increase

the number of patients using efavirenz is one factor behind the decision to seek a CL for this medicine.

¶6. (C) The CL decision can be viewed as the culmination of a long campaign by many health and HIV/AIDS NGOs in Thailand. These groups have long advocated compulsory licenses for ARVs and other patented medicines. As articulated here, the basic NGO argument has been that access to life-saving medicines is directly related to the price of those medicines, that the government should have greater control over supply, and that the commercial interests of for-profit pharmaceuticals firms should take a back seat to saving lives. The contributions of private sector pharmaceuticals companies in fostering innovation in fields like HIV/AIDS treatment is given short shrift, if it is mentioned at all. Opponents of actions such as CL are condemned as money-grubbing foreign capitalists profiteering on the blood of poor and desperately sick Thais. Consistent with this characterization, the Minister of Public Health was hailed in media headlines here for his "brave" decision on CL. We suspect that Thai public opinion on this decision generally is supportive of the Minister.

CL Decision Timeline

¶7. (C) Against this background, a commitment by the RTG to provide ARVs to eligible HIV/AIDS patients and a concomitant concern over rapidly increasing projected costs won sympathy to the idea of a compulsory license among key officials within the MoPH. According to a MoPH contact, earlier this year the National Health Security Office (NHSO), a semi-independent institution that manages Thailand's universal health care coverage program, made the initial proposal to the MoPH. The former Minister accepted that something had to be done and appointed a subcommittee to further examine the issue. MoPH later brought in related agencies including the Department of Intellectual Property to provide legal advice. After the September 19 coup, the new Minister picked up the issue and moved it forward to a decision to issue the license. Foreign Minister Nitya

Pibulsonggram told DCM that the MoPH later presented the decision to the cabinet as a done deal. We do not believe the Cabinet was made aware of the potential significance of this decision, particularly with regard to its potential impact on the perceived foreign investment climate in Thailand.

¶8. (C) The decision has the hallmarks of new MoPH Minister Mongkol Na Songkhla's personal involvement. A medical doctor by training (he received some of his graduate training in the Netherlands), Mongkol is a lifelong civil servant. He rose up through the ranks of the RTG health services, serving much of his early years as a medical officer in some of Thailand's poorest rural districts. This experience has, evidently, made him an ardent supporter of public morals campaigns and laws, especially in the area of alcohol abuse. His efforts have not always been well received by the easy-going Thais. As Minister, his recent "clean up the town" initiatives include a proposed ban on alcohol advertising, and raising the legal drinking age to 25. The latter proposal was particularly poorly received. Critics have stated that besides being out of touch with public opinion, such far-reaching proposals go beyond the appropriate brief of an appointed, interim government. One of his closest aides is Senior Adviser on Health Economics Suwit Wibulpolprasert, a strong ally of HIV/AIDS NGOs here and, we believe, a strong advocate of the NGO agenda on provision of HIV/AIDS medicines.

Do we have a CL?

¶9. (C) There remains some confusion among the RTG and observers as to whether the MoPH has in fact issued a compulsory license. In their November 29 statement, the MoPH stated that the Ministry "exercised the right" against efavirenz "by giving the right to the Government Pharmaceutical Organization". The first of the Ministry's self-imposed conditions on the compulsory license was that "the right shall be applied immediately...." The Department of Intellectual Property termed this as a statement of intent rather than the actual compulsory license. However, MoPH statements to the press have not mentioned any further steps in the licensing process they believe they need to take to begin importing or producing generic efavirenz, nor any

intention to further negotiate with Merck as the patent holder.

¶10. (C) The MoPH statement listed three conditions for the license:

a) The right shall be applied immediately and end by December 31, 2011; (Note: Merck's patent expires in 2013.)

b) Provision of the drug will be enough for not more than 200,000 HIV-infected people per year, exclusively for infected people who are eligible under the National Health Security Act, insured persons under the Social Insurance Act and eligible persons under the government welfare on health for officials and employees; (Note: these three programs together cover the overwhelming majority of Thais.)

c) Royalty fee to be paid to the patent holder shall be set at not more than 0.5 percent of trade value of the generic drug by the GPO.

¶11. (C) The statement also declares that the Ministry's Department of Disease Control shall notify the patent holder and DIP without delay. On December 1, Merck picked up the official notification from the Ministry. The letter notifies Merck that MoPH has taken the right to the drug and assigned it to GPO. It does not request any further consultation or negotiation.

The law

¶12. (C) MoPH's statement cited Section 51 of the Thai Patent Act for authority to issue the license. Under Section 51, a government entity may issue a compulsory license "(i)n order to carry out any service for public consumption or which is of vital importance to the defense of the country, or the preservation or acquisition of natural resources or environment or to prevent or alleviate a severe shortage of food or medicines or other consumer goods and foodstuffs, or for the sake of other public interests." DIP sources say MoPH is using the latter, acting "for the sake of public interests."

¶13. (C) There are a number of drafting flaws in Sections 46-51 that cover compulsory license procedures which make it difficult to interpret what is the proper procedure for issuing a compulsory license under Section 51. For example, Article 51 requires that the RTG pay a royalty "under Section 48, paragraph 2." Section 48 states that "the patentee is entitled to a royalty under Sections 46, 47 and 47bis"; however, Section 51 specifically states that compulsory licenses issued under that article shall not be subject to the provisions of Sections 46, 47 and 47bis.

¶14. (C) As to timing and pre-negotiation, the first paragraph of Section 51 appears to allow a government entity to exploit any patented invention and later "inform the patentee in writing without delay." The second paragraph of Section 51 requires the government entity to "submit its offer setting forth the amount of royalty and conditions for the exploitation to the Director-General (of DIP). The royalty rate shall be as agreed upon by the (government entity) and the patentee, and the provisions of Section 50 shall apply mutatis mutandis." The RTG would appear to have followed these procedures by (1) announcing the compulsory license, (2) notifying Merck in writing and (3) then entering into negotiations solely relating to the royalty amount. This appears to be the DIP's interpretation of Section 51.

¶15. (C) However, Merck's local legal counsel believes that the language applying Section 50 mutatis mutandis could be reasonably interpreted as requiring the following: (1) MoPH applies to DIP to authorize the compulsory license, (2) MoPH and the patentee enter into royalty negotiations mediated by DIP, (3) either the parties agree on a royalty or DIP sets the royalty, and (4) DIP issues a compulsory licensing certificate. The problem with this interpretation is that the procedures laid out in Section 50 relate back to licenses granted under Sections 46, 47 and 47bis. Again, Section 51 specifically states that compulsory licenses issued under that article shall not be subject to the provisions of Sections 46, 47 and 47bis.

¶16. (C) When asked why MoPH had not approached Merck to

request authorization on reasonable commercial terms as required by the WTO TRIPs Article 31, DIP responded that MoPH is using exceptions under Article 31(b) for "public non-commercial use." (NOTE: Embassy has seen a Reuters News press report quoting MoPH officials that "informal talks" to get a lower price from Merck had failed. Merck flatly denies that any such talks have taken place.)

Getting behind the price and supply issues

¶17. (C) In their statement announcing the compulsory license, MoPH gave as their rationale that the patent on efavirenz had kept the price double that of comparable generics and posed an obstacle to access to drugs for HIV patients. They pointed to availability of alternative generics at 700 baht per month per patient, half the price the RTG pays for Merck's patented version.

¶18. (C) The Government Pharmaceutical Organization (GPO), a state-owned profit generating enterprise, would be responsible for importing the drug. GPO officials have not been forthcoming on precisely where and under what pricing conditions they would import efavirenz, but have mentioned India as the likely source. GPO is reportedly under orders from the MoPH to keep the final price of efavirenz to 700 baht. Earlier this year, Indian generic producers Ranbaxy and Cipla announced that they would make generic efavirenz available to developing countries for USD 240 per year. At the current exchange rate, the price for Thailand would be approximately 710 baht per month. However, the listed price is F.O.B. and the final delivery price including shipping and customs charges would likely be closer to 800-850 baht per month. Thai Food and Drug Administration (FDA) says that FDA approval could be waived but that GPO is moving through the process anyway and could win approval through FDA's expedited process in a matter of weeks.

¶19. (C) Merck claims that they sell to the MoPH for 1310 baht per month, plus 7.5 percent VAT, approximately 1400. However, they also sell directly to NGOs for 1040 baht, the higher RTG price reflecting additional local costs imposed by the RTG. Merck has told us that higher production rates for efavirenz have provided greater economies. If asked by the RTG, Merck says that it could negotiate away some of the additional local costs and work the price down to 850 baht, close to what the RTG would pay to import a generic version.

¶20. (C) The GPO has reportedly already developed efavirenz and is in the process of testing and doing bioequivalence studies (the drug compound is easily replicable). GPO officials said they hoped to begin local production of efavirenz by June, 2007. MoPH's statement quoted GPO's chairman that it could produce efavirenz for 700-800 baht for a monthly treatment of 30 pills. It also put expected production capacity at 5 million pills, enough to treat approximately 14,000 patients annually. GPO's actual costs will not be known until production begins, but Embassy notes that an ARV pricing guide put out in 2005 by Medecins Sans Frontieres shows GPO as a consistently high cost producer in comparison to Indian generic producers, typically double the price for the most common ARVs. Whether GPO can bring their costs for efavirenz equivalent to those of the Indians is questionable.

¶21. (C) Although GPO has yet to pass a U.S. FDA or WHO certification process, U.S. CDC says the quality of GPO's antiretrovirals is sufficient. Responses to ARV treatment have been as good as any program in the U.S. and levels of resistance development are within an acceptable range. Nevertheless, the lack of certification excludes GPO from participating in the President's Emergency Plan for Antiretrovirals (PEPFAR). The Global Fund is also restricted from purchasing GPO-produced ARVs, and purchases only FDA- and WHO-approved second line ARVs for use in Thailand.

Supply Problems?

¶22. (C) Separately, Medecins Sans Frontieres (MSF), the health NGO that has promoted issuance of compulsory licenses, maintained that there were also supply issues with Merck's provision of efavirenz, adding another reason to issue a CL. Paul Cawthorne, MSF's Head of Mission in Bangkok, told Econoff they had documented cases of shortfalls at hospitals

that had resulted in treatment interruptions for HIV patients. Hospitals have occasionally called on MSF to provide from their own meager stocks of efavirenz to meet these shortfalls. MSF's own investigation concluded that the sharp increase in demand for efavirenz worldwide had strained Merck's supply chain and had resulted in shortages. Merck's local representatives acknowledged the increase in global

demand in recent years (Thailand itself went from 2,000 to over 20,000 patients on efavirenz in three years) that had stretched global supplies. In 2004 in Thailand there was one instance of a supply interruption, but Merck claims the problem was MoPH's inability to conclude a contract in time rather than a lack of available supply. Merck insisted that Thai hospitals had never suffered shortfalls due to Merck's inability to supply the drug. They did not dispute that hospitals may have occasionally run dry of efavirenz, but suggested the blame lies with gaps in MoPH's own domestic distribution system. Merck noted that at no time has the RTG approached them to discuss supply issues regarding efavirenz.

Proposed Actions

¶23. (C) Notwithstanding what is probably an overwhelmingly pro-CL public opinion climate here, consensus on the wisdom of the compulsory license is not universal within the RTG. Merck says its first notification of the MoPH's intention was from a staffer at the Ministry who disagreed with the decision and hoped Merck could squelch it in time. MoC and MFA contacts have also been less than enthused with the compulsory license decision. Some officials in these (and, probably, other) ministries are likely to view the CL decision as the latest uncoordinated move by the increasingly controversial Minister of Public Health.

¶24. (C) From a trade policy viewpoint, we have always regarded the great value of the CL card as providing leverage in governments' negotiations with pharmaceutical firms on pricing. Used with skill, the CL card can be used to obtain lower prices while avoiding the costs and other problems inherent in setting up new manufacturing or import arrangements. What we find odd in this case is that the RTG evidently never entered into price negotiations with Merck. We suspect that the economic ministries of the RTG would also find this odd (we doubt they are currently aware of these details). Merck's offer to reduce its price for efavirenz may convince the RTG it remains in their interest, financial and otherwise, to keep the patent intact and continue to source the original ARV directly from the company. Keeping the compulsory license open would give the RTG a face-saving way out, allowing the Ministry to chalk up a success in reducing the price of the drug while maintaining the option to produce and/or import if supply problems ever arose.

¶25. (C) As our first proposed action, we suggest that senior Embassy officers brief the appropriate RTG ministries on the details of this issue, and suggest that the RTG enter into price negotiations with Merck. (We will stress that we are not questioning the legal right of Thailand with regard to issuance of a CL.) Such a move would be in the spirit of the WTO's CL provisions (which envision the CL option as being a last resort); is fair given the considerable assistance Merck has provided to Thailand over the years; would send the right signal to other foreign investors; and could well lead to an economically optimal solution for Thailand.

Better Public Outreach, Please

¶26. (C) On this issue, for-profit medicines providers have been completely outmaneuvered in Thailand. Their role in saving lives through innovation has been almost totally obscured, replaced with the image of rich foreigners taking advantage of sick, defenseless Thais. Taking control of technology through a CL is, in this climate, perceived as a brave (and virtuous) act. In previous discussions with PhRMA representatives, we were told that most PhRMA companies believe that the issue of medicines IP is not of interest to the majority of Thais, and that a broad-based public outreach campaign would only serve as a lightning rod for opponents and make the situation worse. We believe that Thailand has emerged as a front-line state on the medicines IP issue and, notwithstanding the relatively small market here, merits increased attention by PhRMA. The placement of additional PhRMA public relations resources in Thailand is fully

justified, in our view.

¶27. (C) There is some urgency to our call for additional resources. The MoPH has announced its intention to issue compulsory licenses on other ARVs, most notably lopinavir/rotinavir, sold under the brand name Kaletra, a second-line ARV produced by U.S.-based Abbott Laboratories. At approximately 7000 baht per month, the treatment is seven times more expensive than available first-line treatments. As HIV-positive patients build resistance to initial treatments, a growing percentage will need to move to more expensive second-line treatments such as Kaletra. The World Bank recently predicted that continuation of Thailand's policy of providing HIV/AIDS medicines to all eligible patients would raise overall health costs by 23 percent, and noted Thailand could save upwards of USD 3.2 billion over the next 20 years by using compulsory licenses. Although price negotiations may save Merck's patent this round, it is quite likely that the RTG will seek a compulsory license again in the near future.

¶28. (C) Action requested: We are unable to hazard a guess on the likelihood of success of our proposed actions; some knowledgeable observers here believe we are facing a fait accompli. In any case, we think we have a strong case to make to the RTG on this issue. That fact, plus the considerable stakes involved for U.S. pharmaceuticals firms, convinces us that the effort is worthwhile. Therefore, Embassy requests Washington agencies' concurrence as soon as practicable on the actions outlined in para 25.
BOYCE